MHA Health Care

Pharmaceutical Waste Management Guide











Why be concerned about pharmaceuticals?

Pharmaceuticals are drugs that are used to treat human and animal ailments. Some pharmaceuticals are toxic (chemotherapy agents) while others function to cause more limited physiological changes. Unused pharmaceuticals are problematic because they do not readily break down once released into the environment. As such, they generally remain intact and can be absorbed by other plants, animals, and/or humans.

What is the environmentally preferred disposal option for unused pharmaceuticals? The preferred disposal method for unused pharmaceuticals is incineration. Incineration is preferred because of its high burn temperatures and effective emission-control systems, which prevent unused drugs from cycling back into our water.



Incineration of pharmaceuticals prevents unused drugs from entering our water.

Why was the Michigan Health and Hospital Association (MHA) Health Care Pharmaceutical Waste Guide developed? There are many different regulations that apply to the hundreds of thousands of pharmaceuticals manufactured today. Under the U.S. Environmental Protection Agency (U.S. EPA) and the Michigan Department of Environmental Quality (MDEQ) environmental regulations, unused medications that can no longer be used for their original intended purpose are a waste. Waste pharmaceuticals from Michigan businesses can be classified as a hazardous waste, liquid industrial waste, non-hazardous solid waste, or a mixed medical waste (also referred to as "dual" waste). The waste classification depends on the character, nature, and composition of the waste. It also depends on what types of waste are mixed together. Because pharmaceutical waste is a common waste, the MDEQ has established pharmaceutical waste as a universal waste type that can be managed under streamlined hazardous waste standards. Complicating the waste classification determination further is the fact that the less hazardous waste a site generates, the less regulation they must meet and the more disposal options available to the site. To determine the level of management that must be met and how pharmaceuticals must be disposed, each site must characterize each of their waste streams, evaluate how the waste is mixed with other waste types. and determine how much hazardous waste is generated on a monthly basis. Based on this information, they can determine the waste classification. Ultimately, pharmaceutical waste should not be mixed with regulated medical waste unless a specific decision to do so is made as it results in the highest disposal cost due to the additional management requirements that must be met. When evaluating a site's hazardous waste generator status, hazardous waste from medical and diagnostic tests and services (e.g., xylene, methanol, etc.); from histology, cytology, pathology, and chemistry; from building maintenance (fluorescent bulbs, batteries, computers, and degreasing solvents); and from pharmaceutical preparation (infusion/dispensing, and vaccinations) all need to be evaluated for inclusion in the monthly hazardous waste generator status determination, which must be documented to prove the management standards a site must meet when managing hazardous waste.





Navigating environmental requirements, controlled substance regulations, medical professional licensing, and the occupational safety drug handling requirements is complicated enough as it is. Add to that all of the newly developed pharmaceuticals, each with many different names and dosages, and you have an especially daunting task of determining how to manage pharmaceutical waste. This guide is meant to simplify the process of determining the management standards that apply to pharmaceutical and regulated medical waste in a manner that advocates a practical approach to incinerating pharmaceuticals as a best management practice (BMP). This guide provides *target compliance options* for meeting the waste regulations in a manner that will facilitate proper handling for meeting the many other requirements that apply to pharmaceuticals in a health care setting. This guide provides a *tool* to quickly evaluate how to meet the laws and regulations set forth by the many governing bodies. Most significantly, this guide simplifies the actions health care facilities can take to protect patients and employees, as well as current and future generations from exposure to harmful substances used in health care.

How do I use this waste guide? This guide does <u>not</u> create any new regulatory requirements that a health care facility must meet. This guide is a tool that provides target compliance options a health care facility can use for managing pharmaceutical and regulated medical waste. This guide advocates the use of best practices. This guide focuses <u>strictly</u> on the <u>environmental</u> waste storage, transportation, and disposal requirements for handling *bulk hazardous pharmaceutical waste, trace chemotherapy waste, universal waste pharmaceuticals, non-hazardous pharmaceutical waste, and mixed medical/dual waste.* Moreover, this guide assumes that any health care facility using this guide is in compliance with the environmental requirements for waste characterization, personnel training, contingency planning, biennial reporting, regulated medical waste management planning, as well as any other requirements that may apply. To gain a general understanding of the environmental regulations related to hazardous and non-hazardous liquid waste that apply to all Michigan businesses, please go to www.michigan.gov/deqworkshops, select "DEQ Online Learning Curriculum" and view the MDEQ online, on-demand recorded "Introduction to Hazardous Waste Regulation Webinars."

To ensure a successful pharmaceutical waste management program, health care facilities should consider using the ten step process for managing pharmaceutical waste. To develop a pharmaceutical waste management program, each health care facility must first characterize their entire pharmaceutical inventory, along with other hazardous and non-hazardous liquid waste, and maintain a record of each waste determination. For pharmaceuticals, this requires a waste characterization determination for each pharmaceutical at each dosage. Newly purchased pharmaceuticals must be added to the pharmaceutical inventory and characterized when they become a waste. After characterizing, the facility must evaluate on a continuous, monthly basis whether the pharmaceuticals they generate that are defined as hazardous waste and must be managed in accordance with the hazardous waste regulations. This is determined by calculating the amount of hazardous waste generated at the facility (all contiguous property under the same ownership) each month, or "determining the facility's hazardous waste generator status." Only waste specifically approved for discharge to the sanitary sewer by the local sanitary sewer authority may be disposed down the drain. Moreover, heavy loading of pharmaceuticals to on-site septic systems, especially chemotherapy agents, can quickly cause even newly installed septic systems to fail. The pharmaceuticals take a huge toll on bacterial action in a septic tank. As such, the use of on-site septic systems at health care facilities with high levels of pharmaceutical use should be avoided.





In choosing the management standards that best suit a facility's circumstances, a facility may segregate hazardous waste pharmaceuticals from non-hazardous pharmaceuticals or commingle all pharmaceuticals. If **segregating** pharmaceutical waste under this guide, the bulk hazardous pharmaceutical, trace chemotherapy, non-hazardous pharmaceutical, and mixed medical/dual waste guide sheets would be used. If **commingling** pharmaceutical waste under this guide, the universal pharmaceutical, trace chemotherapy, and mixed medical/dual waste guide sheets would be used. If segregating pharmaceuticals under this guide, waste *collected* in accordance with the bulk hazardous pharmaceutical guide sheet that does <u>not</u> include spill cleanup waste and does <u>not</u> include contaminated personal protective equipment may be *managed* in accordance with the universal waste guide sheet. This would minimize the volume of pharmaceutical waste counted in determining generator status while providing the facility with the benefits afforded under the universal waste standards (e.g. allow for the collected waste to be accumulated/stored for up to a year and the weight of the waste would not need to be included when determining generator status).

Presently, only about 15 percent of a pharmacy's inventory is defined as a hazardous waste. However, the U.S. EPA is in the early stages of rulemaking to expand the list of pharmaceuticals defined as a hazardous waste to comport more with the list of hazardous drugs issued by the National Institute for Occupational Safety and Health (NIOSH). This action is of increasing importance in light of the Office of Inspector General's findings in May 2012 that the U.S. EPA's inaction to expand this list may be resulting in unsafe disposal. In light of these factors and the knowledge that pharmaceuticals are persistent in the environment, this guide advocates managing all NIOSH hazardous drugs, pharmaceuticals defined as a hazardous waste, and investigative chemotherapy agents in accordance with the hazardous waste regulations as a BMP. Moreover, commingling hazardous and non-hazardous pharmaceuticals and managing them as a universal waste destined for hazardous waste incineration is the best environmental disposal option with the least long term impact on the environment. Segregated hazardous waste, as mentioned above, may also be managed as a universal waste to lessen the impact on generator status.

When considering the overhead cost associated with segregation (e.g., increased generator status, increased labeling, and increased container maintenance, training, etc.), commingling may ultimately be the most cost effective option, even when considering the increased disposal cost. This is particularly true for facilities generating smaller volumes of pharmaceutical waste. Regulated medical waste, which may include trace chemotherapy commingled with regulated medical waste, should not be mixed with pharmaceutical waste so as to minimize disposal costs since mixed medical waste drives a premium cost as a result of the additional handling requirements.

How do I verify that this guide comprehensively serves to meet other pharmaceutical regulations? Consistent with the ten step process for managing pharmaceuticals, health care facilities should consider establishing a team of pharmacy; environmental, health, and safety; housekeeping; and nursing staff to determine what measures work best to handle pharmaceuticals in a manner that satisfies all the requirements that apply in a health care setting. The regulations to be considered would include the U.S. EPA's waste and water regulations, the MDEQ's waste and water regulations, the Michigan Board of Pharmacy's patient safety regulations, the NIOSH and Occupational Health and Safety (OSHA) worker safety regulations, the American Nurses Association's worker safety regulations, any hospital accreditation agency's regulations, and the U.S. Drug Enforcement Administration's (U.S. DEA's) controlled substance regulations. Be sure to coordinate with your disposal vendor(s) and ensure they understand how you are collecting and managing your pharmaceutical and regulated medical waste in order to ensure your facility meets the





various regulations for managing your waste, including the U.S. Department of Transportation (U.S. DOT) regulations.

What regulations and guidelines were considered in creating this guide? The federal Resource Conservation and Recovery Act (RCRA) and Title 40, Parts 260-279, of the Code of Federal Regulations (40 CFR 260-279); Part 111, Hazardous Waste Management, of the Natural Resources and Environmental Protection Act 1994 PA 451, as amended (NREPA), and the Part 111 Rules; Part 115, Solid Waste Management, of the NREPA and the Part 115 Rules; Part 121, Liquid Industrial Wastes, of the NREPA, ; Part 138, Medical Waste Regulatory Act, of the Public Health Code, 1978 PA 368, as amended (Act 368), and the Part 138 Rules; Act 138, Hazardous Materials Transportation Act, 1998 PA 138 (Act 138); Part 161, General Provisions, of Act 368; Part 177, Pharmacy Practice and Drug Control, of Act 368 (Board of Pharmacy), and the Part 177 Rules; NIOSH Guidelines for Controlling Occupational Exposure to Hazardous Drugs, OSHA Technical Manual, OSHA 2012 Hazard Communication Standard, 29 CFR 1910.1200(g); and 49 CFR Parts 100-199 (Hazardous Materials and Oil Transportation).

Who do I contact for questions on this guide? Contact the MDEQ, Environmental Assistance Center at 1-800-662-9278 or deq-assist@michigan.gov for questions on this guide related to Michigan's environmental regulations.

The *MHA Health Care Pharmaceutical Waste Guide* is published jointly by the MHA and the MDEQ. This guide is intended for guidance only and may be impacted by changes in legislation, rules, and regulations adopted after the date of publication. The guide makes every effort to help users evaluate how to meet applicable regulations. This guide advocates the use of BMP's. The information in this guide does not constitute the rendering of legal advice. Diligent attention was given to assure that the information presented herein is accurate as of the date of publication; however, there is no guarantee, expressed or implied, that use of this guide will satisfy all regulatory requirements mandated by laws and their respective enforcement agencies. Reliance on information from this document is not usable as a defense in any enforcement action or litigation. The state of Michigan shall be held harmless for any cause of action brought on as a result of using of this publication.





Glossary of Terms -

- 1. **Accumulation area** means a hazardous waste storage area and does not include satellite accumulation area(s). For more information on hazardous waste accumulation, see the hazardous waste accumulation Webinar at www.michigan.gov/deqworkshops, under "DEQ Online Learning Curriculum," and "Introduction to Hazardous Waste Regulations Webinars."
- 2. **Acute hazardous waste** means waste that is an acute hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) as defined in this guide. This includes all P-listed hazardous waste under the Part 111 Rules and all other listed hazardous waste in the Michigan Part 111 rules with a hazard code of "H."
- 3. **BMP** means best management practice.
- 4. Bulk Hazardous Pharmaceutical Waste (Bulk Haz Pharm) is material intended for discard that is not RCRA "empty", NIOSH hazardous drugs, investigative chemotherapy agents, spill cleanup materials from hazardous pharmaceuticals and contaminated personal protective equipment used with hazardous pharmaceuticals. For additional detail on what is a bulk hazardous pharmaceutical waste, please see the Bulk Hazardous Pharmaceutical Waste Guide Sheet provided as part of this guide.
- 5. **Chemotherapy agent** means a chemical used to treat cancer.
- 6. Closed system drug transfer device means a device used for hazardous drug compounding or administration that mechanically prohibits release of the hazardous drug(s) to the environment by containing the drug(s) in a system that prevents escape of the hazardous drug(s) or drug vapor(s) to the environment outside the system. A closed system drug transfer device typically includes a needle within a protective device that functions to contain the hazardous drug.
- 7. Conditionally exempt small quantity generator (CESQG) stands for a Conditionally Exempt Small Quantity Generator of hazardous waste and is a site that generates less than 100 kilograms or 220 pounds of non-acute hazardous waste and less than 2.2 pounds of acute hazardous waste in a <u>calendar month</u>. CESQG's never accumulate over 1,000 kilograms or 2,200 pounds of non-acute hazardous waste or 1 kilogram or 2.2 pounds of acute hazardous waste <u>at any time</u>.
- 8. **Contingency plan** is a plan for responding to an emergency situation (spill, fire, explosion, etc.) posed by the hazards associated with the waste handled at a site. Contingency planning requirements include a requirement to coordinate with local emergency planning officials for small and large quantity generators of hazardous waste.
- 9. **DEA** means Drug Enforcement Administration.
- 10. **DOT** means United States (U.S.) Department of Transportation.
- 11. **Dual Waste**, also commonly known as "mixed medical waste," means a mixture of regulated medical waste that is infectious waste and hazardous waste or non-hazardous liquid waste that is subject to Part 138 of Act 368 and Part 111 of Act 451 or Part 138 of Act 368 or Part 121 of Act 451, respectively. Mixed medical waste must be managed to meet all of the waste regulations that apply (e.g., a mixture of hazardous pharmaceuticals and infectious regulated medical waste must be managed to meet both the hazardous waste and regulated medical waste regulations). For additional detail on what is a dual or mixed medical waste, please see the Mixed Medical/Dual Waste Guide Sheet provided as part of this guide.
- 12. **Hazardous Pharmaceuticals** as used in this guide includes NIOSH hazardous drugs, pharmaceuticals that are a RCRA hazardous waste as defined in this guide (includes Part 111 Michigan hazardous waste), and investigative chemotherapy agents.





- 13. Hazardous Waste is any waste that is a RCRA listed or characteristic hazardous waste (includes Part 111 Michigan hazardous waste as defined in this guide). Hazardous waste discharged via an authorization issued by the local sanitary sewer authority to the sanitary sewer is no longer a hazardous waste at the point of discharge to the sanitary sewer. For more information on the definition of hazardous waste, see the waste characterization and generator status Webinar at www.michigan.gov/deqworkshops under "DEQ Online Learning Curriculum," and "Introduction to Hazardous Waste Regulations Webinars."
- 14. **Hazardous waste generator status** is determined by counting the weight of all the hazardous waste generated at a site in a <u>calendar month</u>. There are three generator categories under the RCRA: Large Quantity Generator (LQG), Small Quantity Generator (SQG), and Conditionally Exempt Small Quantity Generator (CESQG). A site's hazardous waste generator status is used to determine the handling and disposal requirements the generator must meet. The more hazardous waste a site generates, the more handling requirements must be met. When calculating a site's hazardous waste generator status, the weight of hazardous waste managed in accordance with the Michigan universal waste regulations is not included. For more information on hazardous waste generator status, see the Webinar at www.michigan.gov/deqworkshops under "DEQ Online Learning Curriculum," and "Introduction to Hazardous Waste Regulations Webinars."
- 15. **Inspection log** means a record documenting hazardous waste tank (daily) and/or container accumulation area(s) (weekly) inspections to verify there is/are no release(s) and/or to respond to release(s) required of SQG storing greater than 2,200 pounds non-acute hazardous waste and LQG facilities, not CESQG or universal waste handlers.
- 16. **IV** means intravenous, within a vein, or administering by injection into a vein. When referring to an "IV" in healthcare, the reference is commonly used to describe a bag of fluid that is to be administered to the patient intravenously.
- 17. Land Disposal Restrictions (LDR's) are rules that require hazardous waste to be treated prior to being disposed on land to destroy or immobilize hazardous constituents that might migrate into soil and ground water. The LDR's require that SQG's and LQG's provide notification to each destination facility prior to shipment for each hazardous waste. The notification must state whether the waste must be treated prior to being land disposed and identify the underlying hazardous constituents in the waste requiring treatment.
- 18. Large Quantity Generator (LQG) stands for Large Quantity Generator of hazardous waste. An LQG is a site that generates equal to or greater than 1,000 kilograms or 2,200 pounds of non-acute hazardous waste and/or equal to our greater than 1 kilogram or 2.2 pounds of acute hazardous waste in a <u>calendar month</u>; or accumulates 1 kilogram or 2.2 pounds or more of acute hazardous waste <u>at any given time</u>. Beyond meeting the SQG requirements, all LQG's must also have:
 - a) Secondary containment for the hazardous waste storage area(s),
 - b) More elaborate recordkeeping,
 - c) More elaborate training, and
 - d) Established and maintained a contingency plan for emergencies

LQG's must meet the land disposal restrictions. LQG's must also submit a biennial report and pay higher handler and manifest fees. LQG's may store hazardous waste on-site for up to 90 days without obtaining a hazardous waste storage license if the LQG accumulation/storage requirements are met.

19. Liquid industrial waste means all liquid waste generated by a business that is not specifically excluded from the definition of liquid industrial waste and is not listed as "materials not specified as liquid industrial waste." Liquids discharged via an authorization issued by the local sanitary





- sewer authority to the sanitary sewer are no longer a liquid industrial waste at the point of discharge to the sanitary sewer.
- 20. **Manifest** means a Uniform Hazardous Waste Manifest form used for tracking waste from the site of generation to the site of treatment or disposal.
- 21. **Medical waste** is referred to herein as regulated medical waste. See the regulated medical waste definition.
- 22. Medical Waste Management Plan All medical waste producing facilities as defined under Part 138 of Act 368 must have a medical waste management plan that lists and describes the type(s) of regulated medical waste produced by the facility and the method(s) of packaging, storage, treatment, and disposal implemented to minimize exposure to infectious agents. An example plan is online at www.michigan.gov/deqmedwaste.
- 23. Mixed Medical Waste, also commonly known as "dual waste," means a mixture of regulated medical, infectious waste, and hazardous waste or non-hazardous liquid waste that is subject to Part 138 of Act 368 and Part 111 (Hazardous Waste) of Act 451 or Part 121 (Liquid Industrial Waste) of Act 451, respectively. Mixed medical waste must be managed to meet all of the waste regulations that apply (e.g. a mixture of hazardous pharmaceuticals and infectious regulated medical waste must be managed to meet both the hazardous waste and medical waste regulations). For additional detail on what is a mixed medical or dual waste, please see the Mixed Medical/Dual Waste Guide Sheet provided as part of this guide.
- 24. **Non-empty** means a container that has residue subject to the RCRA. See empty definition for clarification on when empty is achieved under the RCRA.
- 25. **Non-Hazardous Pharmaceutical Waste (Non-Haz Pharm)** means pharmaceuticals that are <u>not</u> a listed or characteristic RCRA waste, a NIOSH hazardous drug, or an investigative chemotherapy agent. Non-hazardous pharmaceutical waste includes liquid, solid, paste, and aerosol pharmaceuticals. For additional detail on what is a non-hazardous pharmaceutical waste, please see the Non-Hazardous Pharmaceutical Waste Guide Sheet provided as part of this guide.
- 26. **NREPA** stands for the Natural Resources and Environmental Protection Act, Public Act 451 of 1994, as amended.
- 27. **OSHA** stands for Occupational Health and Safety Administration.
- 28. **Part 111** means the Michigan Hazardous Waste Law found under Part 111, Hazardous Waste Management, of the NREPA, as amended, and the Part 111 hazardous waste rules.
- 29. Part 121 means the Michigan Part 121, Liquid Industrial Waste, of the NREPA.
- 30. **Pharmaceutical** means a drug intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or animals.
- 31. **PPE** means personal protective equipment and includes caps, gowns, shoe covers, safety glasses, etc. used to protect people from exposure to hazardous drugs.
- 32. **RCRA** stands for the Resource Conservation and Recovery Act of 1976 and, for the purposes of this guide, includes the requirements of Part 111 and the Part 111 rules.
- 33. Regulated medical waste includes medical waste as defined in the Medical Waste Regulatory Act, Part 138 of Public Health Code, 1978 PA 368, as amended, and the Part 138 rules; regulated medical waste as defined in 49 CFR Parts 100-185 (Hazardous Materials Transportation); AND OSHA Bloodborne Pathogens as defined in 29 CFR 1910.1030. Regulated medical waste as used in this guide includes clinical waste and biomedical waste as defined under the U.S. DOT regulations and is also referenced as biohazardous waste. Regulated medical waste includes any infectious or potentially infectious waste as well as used and unused sharps pursuant to Part 138. Regulated medical waste is required to be placed in medical waste containers conforming with all packaging and labeling requirements described in 49 CFR 173. Regulated medical waste does not include waste pharmaceuticals, hazardous or non-hazardous. If pharmaceutical waste is





mixed with regulated medical waste, the waste is subject to mixed medical/dual waste regulations. Regulated medical waste specifically includes any of the following waste that is not generated from a household, home health care agency, or home for the aged meeting definition of a household found in 49 CFR 171.8 and is not an agricultural product as defined in the Federal Food, Drug, and Cosmetics Act:

- Cultures and stocks of infectious agents and associated biologicals, including laboratory waste, biological production waste, discarded live and attenuated vaccines, culture dishes, and related devices.
- b) Liquid human and animal waste, including blood, blood products, and body fluids, but not including urine or materials stained with blood or body fluids.
- c) Pathological waste.
- d) Sharps.
- e) Contaminated waste from animals that have been exposed to agents infectious to humans, these being primarily research animals.

Regulated medical waste must be decontaminated through autoclaving, incineration, or an alternative method approved by the MDEQ at a facility permitted to accept regulated medical waste. Regulated medical waste mixed with trace chemotherapy waste (a non-hazardous solid waste) must be incinerated. Trace chemotherapy waste should <u>never</u> be treated by autoclaving, due to the emissions and autoclave operator exposure hazards associated with the treatment of materials that may contain chemotherapy agents. If pharmaceuticals are mixed with medical waste, the mixture must be managed to meet the hazardous waste (hazardous pharmaceuticals) or liquid industrial waste (non-hazardous pharmaceutical) regulations <u>AND</u> the regulated medical waste regulations.

- 34. **Reverse distribution/reverse distributor** is a process carried out by a third-party that directs unwanted and outdated pharmaceuticals from health care facilities, including controlled substances in accordance with the U.S. DEA requirements, and returns them to the manufacturer for credit and/or arranges for their disposal.
- 35. Satellite accumulation area (most likely a soiled utility room) means an area that is at or near the point of waste generation, under the operator's (waste generator's) control, and used to accumulate no more than 55 gallons of non-acute hazardous waste or 1 guart of acute hazardous waste at any given time. The satellite accumulation area is where hazardous waste is initially accumulated prior to moving it to the storage area. The SQG and LQG hazardous waste cannot be moved from one satellite container location to another satellite container location. The benefit of using a satellite container is that it is not subject to the 90 or 180 day storage limitation if the site is a SQG or LQG, respectively. Satellite containers at SQG's and LQG's must be legibly labeled with the words "Hazardous Waste:" the hazardous waste number(s) (i.e., P012), the chemical name (i.e., Arsenic Trioxide), or Bulk Haz Pharmaceuticals; and closed when not in use. More than one satellite accumulation container can be used in one location as long as the total volume does not exceed 55 gallons for non-acutely hazardous waste or one quart for acutely hazardous waste. Once the storage capacity limit has been reached, the satellite container(s) must be labeled with an accumulation start date, and the hazardous waste number(s), then moved to the designated storage area with secondary containment (where required) within three days. For more details on satellite accumulation, see Operational Memo 111-2 and discuss your specific circumstance with Local District Office, Hazardous Waste Program staff.
- 36. **Small quantity generator** (SQG) stands for Small Quantity Generator of hazardous waste. A SQG generates more than 100 kilograms or 220 pounds of hazardous waste and less than 1,000 kilograms or 2,200 pounds of non-acute hazardous waste in a <u>calendar month</u>, and less than 1 kilogram or 2.2 pounds of acute hazardous waste in a calendar month. SQG's never accumulate





6,000 kilograms or 13,200 pounds of non-acute hazardous waste or 1 kilogram or 2.2 pounds of acute hazardous waste <u>at any time</u>. SQG's must also meet the <u>land disposal restrictions</u> and pay handler and manifest fees. SQG's may store hazardous waste on-site for up to 180 days without obtaining a hazardous waste storage license if the SQG accumulation/storage requirements are met.

- 37. **Spill,** for purposes of this guide, means any visible hazardous pharmaceutical that was not contained and administered to a patient as intended. Spill generally includes any releasing, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment.
- 38. **Storage area** means the hazardous waste storage area and does not include satellite accumulation area(s).
- 39. **Trace Chemotherapy Waste** (Trace Chemo) includes materials intended for discard that are not known to be contaminated with chemotherapy agents but were used in administering chemotherapy and may have been exposed to chemotherapy agents. This can include empty IV bags, bottles, vials (containers), and syringes. It may also include infectious, biohazardous, regulated medical waste, in which case it must be managed as a regulated medical waste. For additional detail on what is a trace chemotherapy waste, please see the Trace Chemotherapy Waste Guide Sheet provided as part of this guide.
- 40. **TSDF** stands for a hazardous waste treatment, storage, or disposal facility that is licensed under the RCRA to receive hazardous waste for treatment, storage, and/or disposal of the hazardous waste.
- 41. Universal Waste Pharmaceutical (Universal Pharm) means a waste pharmaceutical managed in accordance with streamlined universal waste standards adopted for specific, common, hazardous waste types. Pharmaceuticals have been a universal waste type in Michigan since December 16, 2004, and in Florida since April 22, 2007. Universal Waste Pharmaceuticals include RCRA/Part 111 pharmaceuticals intended for discard, their containers that are not RCRA "empty," NIOSH hazardous drugs, and investigative chemotherapy agents. Non-hazardous pharmaceuticals may be included; however, once mixed, are all subject to RCRA/Part 111 universal waste regulations. Universal Waste Pharmaceuticals include only drugs. It does not include spill cleanup materials from hazardous pharmaceutical spills or contaminated personal protective equipment used with hazardous pharmaceuticals. For additional detail on what is a universal waste pharmaceutical, please see the Universal Waste Pharmaceutical Guide Sheet provided as part of this guide. Note too, that the satellite container requirements for SQG and LQG hazardous waste do not apply to universal waste pharmaceuticals managed under the universal waste standards.
- 42. **Waste characteristic** means ignitable, corrosive, reactive, or toxic as defined under the RCRA and severely toxic as defined under Part 111 of the NREPA.
- 43. Waste characterization is the process of determining the waste type using the steps specified by the RCRA, Michigan's non-hazardous liquid waste regulations, and other applicable waste regulations. Generally, a waste is either a hazardous, liquid industrial (non-hazardous liquid), or non-hazardous solid waste under the waste regulations. However, waste may also be subject to more than one waste regulation if it is also a regulated medical waste (e.g. mixed medical waste/dual waste), radiological waste, or subject to the Toxic Substance Control Act. Michigan also has some additional "U" listed hazardous waste types. When documenting a waste characterization determination, the documents must be available in writing and made available upon request for 3 years from the last date of off-site shipment or on-site treatment or disposal. Commonly, large health care facilities with pharmacies will use the facility pharmacy formulary





(inventory) to document the waste type determination (e.g. hazardous, non-hazardous liquid, non-hazardous solid) then maintain relevant supporting data (e.g. Material Data Safety Sheets, etc.) with other waste records (e.g. manifests, land disposal restriction notices, etc.). As new products, including pharmaceuticals, are used at the health care facility, they must be evaluated to determine how the waste must be handled. For more information on waste characterization, also see the waste characterization Webinar at www.michigan.gov/deqworkshops under "DEQ Online Learning Curriculum," and "Introduction to Hazardous Waste Regulations Webinars."

44. **Waste Data System** is the data system used by the MDEQ to track waste-related activities. It can be accessed at http://www.deq.state.mi.us/wdspi/AdvancedSearch.aspx.





Bulk Hazardous Pharmaceuticals Waste MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Bulk Hazardous Pharmaceutical Waste (Bulk Haz Pharm)?

Bulk hazardous pharmaceutical waste or Bulk Haz Pharm includes pharmaceuticals intended for discard that are a RCRA hazardous waste as defined in this guide, NIOSH hazardous drugs, and investigative chemotherapy agents. Bulk Haz Pharm includes spill cleanup materials from hazardous pharmaceuticals; contaminated personal protective equipment used with hazardous pharmaceuticals; non-empty containers used with hazardous pharmaceuticals (vials, ampules, IVs, bottles, tubing, and syringes with no sharps). Bulk Haz Pharm includes closed system drug transfer devices and sharps used for pharmacy compounding of hazardous pharmaceuticals (non-infectious) if approved by the disposal vendor. Bulk Haz Pharm does not include closed system drug transfer devices or sharps used to administer hazardous pharmaceuticals to patients. Bulk Haz Pharm is not to include fluids and/or devices removed from intracavity installations unless approved by the vendor as non-infectious. Bulk Haz Pharm does not include unused and

RCRA/Part 111 hazardous waste pharmaceuticals

NIOCH bezordene druge



intact pharmaceuticals in their original packaging directed for resale and reuse for its original intended purpose. Check with your disposal vendor to determine whether Mixed Medical/Dual Waste includes closed system drug transfer devices used in hazardous pharmaceutical compounding, sharps used in hazardous pharmaceutical compounding, and fluids and/or devices removed from intracavity hazardous pharmaceutical installations.

What is Included in Bulk Haz Pharm?

NIOSH hazardous drugs
Investigative chemotherapy agents
P-listed hazardous waste pharmaceuticals
Non-empty containers, including vials, ampules, IVs, bottles, tubing, and syringes with
no sharps
Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns,
gloves, shoe covers, absorbent pads, absorbent materials)
Contaminated items used in hazardous pharmaceutical compounding
Contaminated PPE used in hazardous pharmaceutical compounding and
administration
Pharmacy containers that held hazardous pharmaceuticals
Closed system drug transfer devices and sharps used in pharmacy compounding of
hazardous pharmaceuticals with approval as non-infectious by disposal vendor
Fluids and/or devices removed from intracavity hazardous pharmaceutical installations
with approval as non-infectious by disposal vendor





Note: Empty and non-empty containers (ampules, vials, IVs, and closed system drug transfer devices used in compounding) used with hazardous pharmaceuticals may be segregated from spill materials and managed as universal waste in Michigan. See the Universal Pharmaceutical Waste Guide Sheet.

What is Excluded from Bulk Haz Pharm?

Closed system drug transfer devices and sharps used in pharmacy compounding of hazardous pharmaceuticals *without approval* as non-infectious by disposal vendor

Fluids and/or devices removed from intracavity hazardous pharmaceutical installations *without approval* as non-infectious by disposal vendor

Closed system drug transfer devices and sharps used in administration of a hazardous pharmaceutical to a patient

Empty, undamaged unit dose packaging/containers used to administer P-listed hazardous pharmaceutical compressed or coated tablet(s), capsule(s), and gum to a patient if there are no visible residues in the container (non-hazardous solid waste)

Note: For excluded Bulk Haz Pharm items without vendor approval as non-infectious, see the Mixed Medical/Dual Waste Guide Sheet

Container

- Constructed of material that is compatible with the waste
- Spill, leak, and puncture-proof
- Kept closed except during active addition or removal of waste to/from the container
- Meet the DOT packaging regulations
- Separate incompatibles (ignitables and oxidizers)

Satellite Area and Labeling

- Label with words "Hazardous Waste"
- Label waste as "Bulk Haz Pharmaceuticals" or chemical name
- Move satellite container to storage area when full or within three days of collecting one quart of acute hazardous waste or 55 gallons of non-acute hazardous waste, whichever occurs first
- Label with accumulation date and waste codes when moved to storage area



Accumulation Label

Storage and Transportation

- Maintain label as "Hazardous Waste"
- Maintain label with content waste code(s)
- Maintain label with accumulation date
- Protect from weather, fire, physical damage, and vandals
- Separate incompatibles
- Inspect weekly
- Provide secondary containment for liquids
- Do not store over 90 days (LQG) or over 180 days (SQG)



Shipping Label





- Transport using permitted/registered hazardous waste transporter
- Use Uniform Hazardous Waste Manifest as shipping document
- Comply with DOT requirements
- Attach proper shipping label for transport

Disposal

- Bulk Haz Pharm must be transported to a licensed hazardous waste TSDF in Michigan, an out-of-state equivalent facility, or a facility otherwise authorized to accept hazardous waste pharmaceuticals
- Incineration is the BMP for all pharmaceuticals
- Incineration at a licensed hazardous waste TSDF is required for P-listed and U-listed RCRA pharmaceuticals and any pharmaceuticals mixed with P-listed or U-listed RCRA pharmaceuticals per the RCRA Land Disposal Restriction requirements

Record-Keeping

- Maintain records at least three years
- Waste characterization determination (most likely from facility pharmaceutical formulary analysis) and support records (MSDS)
- Monthly waste inventory
- Land disposal restriction notifications
- Maintain Uniform Hazardous Waste Manifest copies and send copy to the MDEQ by 10th day of month following shipment
- Accumulation area inspection logs
- Training records

Note: Materials managed as Bulk Haz Pharm must be included in the monthly hazardous waste generator status determination.





Trace Chemotherapy Waste MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Trace Chemotherapy Waste (Trace Chemo)?

Trace Chemotherapy Waste or Trace Chemo includes solid materials intended for discard that are **not** known to be contaminated with chemotherapy agents but were exposed to chemotherapy agents and are **not** a hazardous waste. This material includes uncontaminated personal protective equipment and empty packaging, vials, ampules, IVs, bottles, and tubing. These materials do not include hazardous pharmaceutical or chemotherapy agent spill cleanup materials. Trace Chemo may include regulated medical waste like syringes used in administration of chemotherapy agents. Where desirable, like large infusion clinics. Trace Chemo waste can be combined with biohazardous, regulated medical waste to eliminate the need for additional containers. However, if biohazardous, regulated medical waste is combined with uncontaminated PPE and empty chemotherapy containers (non-hazardous solid waste), Trace Chemo must be incinerated at a facility authorized to accept non-hazardous solid waste and regulated medical waste, and the containers must be properly labeled and managed as a biohazardous, regulated medical waste.



Trace Chemo without medical waste

What is Included in Trace Chemo?

Pharmacy items, except containers, tubing and sharps, not known to be contaminated and used in preparation of chemotherapy agents like:

PPE (gowns, gloves, bouffant caps, shoe covers)

Absorbent pads

Disposable wipes

Empty hazardous pharmaceutical containers, including vials, ampules, IVs, bottles, and tubing

Nursing items not known to be contaminated and used in administration of chemotherapy agents like:

PPE (gowns, gloves, bouffant caps, shoe covers)

Absorbent pads

Disposable wipes

Closed system drug transfer devices and sharps used in administration of a chemotherapy agents to a patient (medical waste)¹

Where desirable, like large infusion clinics, Trace Chemo waste can be combined with regulated medical waste to eliminate the need for additional containers. However, the combined waste must be <u>incinerated</u> at a facility authorized to accept non-hazardous solid waste and regulated medical waste and the containers must be properly labeled and managed as an infectious, biohazardous, regulated medical waste.



Biohazard Symbol





What is Excluded from Trace Chemo?

RCRA/Part 111 hazardous waste pharmaceuticals

Non-hazardous liquid and solid pharmaceuticals unless the incinerator is authorized to incinerate non-hazardous pharmaceuticals

NIOSH hazardous drugs

Investigative chemotherapy agents

Pharmacy items like:

Contaminated items used in hazardous pharmaceutical compounding Non-empty containers used in hazardous pharmaceutical compounding

Acute hazardous waste containers used for compounding

Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, bouffant caps, shoe covers, absorbent pads, disposable wipes)

Closed system drug transfer devices and sharps used in compounding hazardous pharmaceuticals

Nursing items used in hazardous pharmaceutical administration like:

Partially filled/infused hazardous pharmaceuticals including bags, bottles, and tubing

Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, shoe covers, absorbent pads, absorbent materials, and bouffant caps)

Fluids and/or devices removed from intracavity hazardous pharmaceutical installations

Non-empty hazardous pharmaceutical containers

Note: Items excluded from Trace Chemo must follow appropriate hazardous waste disposal requirements and be managed as Bulk Haz Pharm, Universal Waste Pharmaceutical, Non-hazardous Pharmaceutical, or Mixed Medical/Dual Waste Guide Sheets.

Container

- Compatible with the waste
- Spill, leak, and, if containing regulated medical waste, puncture-proof
- Kept closed except during active addition of waste to container
- Meet the DOT packaging regulations

Satellite Area and Labeling

- Label container "Trace Chemo Incineration Only" or "Trace Chemo & Medical Waste Incineration Only"
- Move sealed containers to storage area within three days of container being three-fourths full (routinely) if containing regulated medical waste
- Date container when waste is first added to the container
- Schedule pickup when full or 90 days from date when use of container initiated
- Close when not actively adding waste
- Satellite area must be secured from unauthorized access to waste





Storage Area

- Secure from weather, fire, physical damage, and vandals
- Inspect weekly
- Do not store over 90 days from date of first use of container (satellite and storage combined)
- Maintain label

Transportation

- Comply with the DOT requirements
- Attach proper shipping label
- Use a properly prepared shipping document, generally bill of lading

Record-Keeping

- Shipping papers or manifest are required to be signed
- Maintain training records
- Inspection of storage areas (BMP)
- Maintain Medical Waste Management Plan

Disposal

- Trace Chemo must be transported to a facility properly licensed or otherwise authorized to accept regulated medical waste, if mixed with regulated medical waste
- Incineration is the BMP for Trace Chemo
- Incineration is required for Trace Chemo mixed with regulated medical waste
- Trace Chemo cannot be treated by autoclave

Trace Chemo & Regulated Medical Waste must be disposed of 90 days from the first day waste is placed in the container. Start date begins when waste is first added to the container.

Note: Trace Chemo is **not** included in the monthly hazardous waste generator status determination.





Universal Waste Pharmaceutical MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Universal Waste Pharmaceutical (Universal Pharm)?

Universal Waste Pharmaceuticals or Universal Pharm includes pharmaceuticals that cannot be used or administered because of expiration, contamination, or any other reason. Universal Pharm may be liquid, solid, paste, or aerosol, and includes drugs identified as U-listed or P-listed hazardous waste, and investigative chemotherapy agents. Universal Pharm includes NIOSH hazardous drugs and drugs



that are not currently regulated but considered hazardous. Universal Pharm includes full or partially used pharmaceutical containers. Universal Pharm does not include infectious, biohazardous, regulated medical waste, pharmaceutical spill cleanup waste, or personal protective equipment contaminated with pharmaceuticals. Universal Pharm does not include unused and intact pharmaceuticals in their original packaging directed for resale and reuse for its original intended purpose. Check with your disposal vendor to determine whether Mixed Medical/Dual Waste includes closed system drug transfer devices used in hazardous pharmaceutical compounding, sharps used in hazardous pharmaceutical compounding, and fluids and/or devices removed from intracavity hazardous pharmaceutical installations.

Note: Universal Pharm can include non-hazardous solid and liquid pharmaceuticals. When non-hazardous pharmaceuticals are mixed with Universal Pharm waste, the entire mixture must be managed as a Universal Pharm.

What is Included in Universal Pharm?

RCRA/Part 111	hazardous waste	pharmaceuticals

NIOSH hazardous drugs

Investigative chemotherapy agents

Non-empty hazardous pharmaceutical containers, including vials, ampules, IVs, bottles, and tubing without sharps

Closed system drug transfer devices and sharps used in pharmacy compounding of hazardous pharmaceuticals *with approval* as non-infectious by disposal vendor

Fluids and/or devices removed from intracavity hazardous pharmaceutical installations with approval as non-infectious by disposal vendor

What is Excluded from Universal Pharm?

Closed system drug transfer devices and sharps used in pharmacy compounding of hazardous pharmaceuticals *without approval* as non-infectious by disposal vendor

Fluids and/or devices removed from intracavity hazardous pharmaceutical installations without approval as non-infectious by disposal vendor

Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, shoe covers, absorbent pads, absorbent materials)

Contaminated items used in hazardous pharmaceutical compounding

Contaminated PPE used in hazardous pharmaceutical compounding and administration





Closed system drug transfer devices and sharps used in administration of a hazardous or non-hazardous pharmaceutical to a patient

Note: For excluded Universal Pharm items without vendor approval as non-infectious, see the Mixed Medical/Dual Waste Guide Sheet

Container and Labeling

- Compatible with the waste
- Separate incompatible materials
- Labeled "Universal Waste Pharmaceutical"
- Kept closed except to add or remove waste
- Meet the DOT packaging regulations
- Date container when waste is first added to container

Satellite and Storage Area

- Be secured from weather, fire, physical damage, and vandals
- Separate incompatible materials
- Inspected weekly (BMP)
- Provide secondary containment (BMP)

Transportation

- Transported using a permitted/registered liquid industrial waste transporter
- Occur within one year of accumulation
- Be in compliance with the DOT requirements
- Accompanied by a Uniform Manifest

Disposal

- Disposal must ultimately include treatment and/or destruction at a hazardous waste TSDF
- Universal Pharm may also be transported to another universal waste handler within the State of Michigan prior to ultimate disposal
- Universal Pharm must ultimately be transported to a licensed hazardous waste TSDF in Michigan, an out-of-state equivalent facility, or a facility otherwise authorized to accept the hazardous waste pharmaceuticals
- Incineration is the BMP for all pharmaceuticals
- Incineration at a licensed hazardous waste TSDF is required for P-listed and U-listed RCRA pharmaceuticals and any pharmaceuticals mixed with P-listed or U-listed RCRA pharmaceuticals per the RCRA Land Disposal Restriction requirements
- Universal Pharm, when managed in Michigan, must be managed in compliance with the liquid industrial waste requirements

Note: The weight of Universal Pharm is <u>not</u> included in the monthly hazardous waste generator status determination. Presently only Michigan and Florida have adopted pharmaceuticals as a universal waste type. Therefore, upon crossing the Michigan state line, Universal Pharm becomes subject to the other state's laws. When manifesting Universal Pharm, note in box 14 of the Uniform Manifest that the waste was managed as Universal Waste Pharmaceutical in Michigan.





Non-Hazardous Pharmaceutical Waste

MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Non-Hazardous Pharmaceutical Waste (Non-Haz Pharm)?

Non-Hazardous Pharmaceutical waste or Non-Haz Pharm includes all pharmaceuticals that are <u>not</u> a listed or characteristic RCRA waste, not a NIOSH hazardous drug, and not an investigative chemotherapy agent. Non-Haz Pharm waste includes liquid, solid, paste, and aerosol pharmaceuticals. Non-Haz Pharm waste does not include unused and intact non-hazardous pharmaceuticals in their original packaging directed for resale and reuse for its original intended purpose.

Safety Some

Note: Conditionally Exempt Small Quantity Generator (CESQG) hazardous pharmaceutical waste may be excluded from regulation as a hazardous waste if records demonstrating the exempt

generator status are maintained and the waste is managed as a Non-Haz Pharm. However, due to their unique handling requirements, CESQG should consult with their disposal vendor to determine how to manage CESQG hazardous waste. Moreover, Non-Haz Pharm waste may be commingled with Universal Pharm waste and managed as a Universal Pharm destined for hazardous waste incineration.

What is Included in Non-Haz Pharm?

N	lon-l	hazaro	lous p	harmaceutic	als ii	n all	torms - li	iquid, so	olid, pas	ste, or aerosol
---	-------	--------	--------	-------------	--------	-------	------------	-----------	-----------	-----------------

Non-hazardous pharmaceutical spill cleanup materials

Household pharmaceuticals

Empty hazardous pharmaceutical containers, including vials, ampules, IVs, bottles, and tubing

What is Excluded from Non-Haz Pharm?

RCRA/Part 111 hazardous pharmaceuticals					
NIOSH hazardous drugs					
Investigative chemotherapy agents					
Non-empty hazardous pharmaceutical containers, including vials, ampules, IVs,					
bottles, and tubing					
Closed system drug transfer devices used in pharmacy compounding or					
administration of hazardous pharmaceuticals					
Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns,					

gloves, shoe covers, absorbent pads, absorbent materials)

Contaminated PDE used in hazardous pharmaceutical compounding and

Contaminated PPE used in hazardous pharmaceutical compounding and administration

Sharps





Infectious materials/biohazardous materials (medical waste) including:

Closed system drug transfer devices and sharps used in administration of a hazardous pharmaceutical to a patient

Fluids and/or devices removed from intracavity hazardous pharmaceutical installations

Pharmacy items like:

Contaminated items used in hazardous pharmaceutical compounding Non-empty containers used in hazardous pharmaceutical compounding Acute hazardous waste containers used for compounding Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, bouffant caps, shoe covers, absorbent pads, disposable wipes)

Nursing items used in hazardous pharmaceutical administration like:

Partially filled/infused hazardous pharmaceuticals including bags, bottles, and tubing

Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, shoe covers, absorbent pads, absorbent materials, and bouffant caps)

Container

- Constructed of material that is compatible with the waste
- Spill, leak, and puncture-proof
- Kept closed except during active addition of waste to the container
- Separate incompatibles
- Meet the DOT packaging regulations

Storage and Labeling

- Label waste as "Non-Haz Pharm"
- Separate incompatibles
- Secure from weather, fire, physical damage, and vandals
- Manage to prevent escape to the environment

Transportation

- Transport using permitted/registered liquid industrial waste transporter unless only solid pharmaceuticals
- Use Uniform Hazardous Waste Manifest as shipping document or other shipping document if only solid pharmaceuticals
- Comply with DOT requirements

Disposal

 Non-Haz Pharm, when transported to a Michigan facility, must be transported to a facility notified as a designated facility receiving liquid industrial waste unless only solid pharmaceuticals





- Disposal must occur at a disposal facility authorized to accept Non-Haz Pharm waste or a licensed hazardous waste TSDF
- Incineration is the BMP for all pharmaceuticals

Record-Keeping

- Maintain records at least three years
- Waste characterization determination (most likely from facility pharmaceutical formulary analysis) and support records (MSDS)
- Monthly waste inventory (generator status records) if managing as exempt hazardous waste
- Maintain Uniform Hazardous Waste Manifest copies and send copy to the MDEQ by 10th day of month following shipment or other shipping document

Note: Non-Haz pharmaceuticals that are not a characteristic or listed hazardous waste and are not CESQG hazardous waste are <u>not</u> included in the monthly hazardous waste generator status determination.





Mixed Medical/Dual Waste MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Mixed Medical/Dual Waste?

Mixed Medical/Dual Waste refers to regulated medical waste mixed with hazardous waste or non-hazardous liquid waste. When regulated medical waste is mixed with waste subject to these regulations, the waste becomes subject to the management standards under both regulations due to the unique hazards associated with biohazardous, regulated medical waste. Regulated medical waste mixed with pharmaceutical waste cannot be autoclaved. Mixed Medical/Dual Waste includes vaccinations with live or attenuated viruses that are a RCRA/Part 111 hazardous waste (e.g. vaccinations preserved with thimerosal) and pharmaceutical waste inadvertently mixed with infectious, biohazardous, regulated medical waste. Check with your disposal vendor to determine



whether Mixed Medical/Dual Waste includes closed system drug transfer devices used in hazardous pharmaceutical compounding, sharps used in hazardous pharmaceutical compounding, and fluids and/or devices removed from intracavity hazardous pharmaceutical installations.

What is Included in Mixed Medical/Dual Pharmaceutical Waste?

Vaccinations with live or attenuated viruses and a RCRA/Part 111 hazardous waste pharmaceuticals (e.g. vaccinations preserved with thimerosal)

Closed system drug transfer devices and sharps used in pharmacy compounding of hazardous pharmaceuticals *without approval* as non-infectious by disposal vendor Fluids and/or devices removed from intracavity hazardous pharmaceutical installations *without approval* as non-infectious by disposal vendor

Pharmaceutical waste inadvertently mixed with infectious/biohazardous materials (regulated medical waste)

What is Excluded from Mixed Medical /Dual Pharmaceutical Waste?

Waste included in the Bulk Haz Pharm, Trace Chemo, Universal Pharm, and Non-Haz Pharm Guide Sheets

Container

- Compatible with the waste
- Spill, leak, and puncture-proof
- Thick, leak-proof liner
- Separate incompatible materials
- Kept closed except during active addition of waste to container
- Meet the DOT packaging regulations
- Date container when waste is first added to container





Satellite Area and Labeling

- Label with words "Hazardous Waste"
- Label container "Pharmaceutical & Medical Waste Incineration Only"
- Locate secure satellite area as near as possible to where waste is generated
- Move satellite container to storage area when full or within three days of collecting one quart of acute hazardous waste, or 55 gallons of non-acute hazardous waste, whichever comes first
- Label with waste codes when moved to storage area
- Do not store over 90 days from date of first use of container (satellite and storage combined)

Storage Area

- Maintain label as "Hazardous Waste"
- Maintain label with content hazardous or liquid industrial waste code(s)
- Maintain label "Pharmaceutical & Medical Waste Incineration Only"
- Protect from weather, fire, physical damage, and vandals
- Separate incompatible materials
- Inspect weekly
- Provide secondary containment
- Do not store over 90 days from date of first use of container (satellite and storage combined)

Transportation

- Transport using permitted/registered hazardous waste transporter
- Use Uniform Hazardous Waste Manifest as shipping document
- Comply with DOT requirements
- Attach proper shipping label

Disposal

- Mixed Medical/Dual Pharm must be transported to a licensed hazardous waste TSDF incinerator in Michigan or an out-of-state equivalent facility that is also authorized to dispose of infectious, biohazardous, medical waste
- Incineration is required for mixed medical/dual waste
- Incineration at a licensed hazardous waste TSDF is required for P-listed and U-listed RCRA pharmaceuticals and any pharmaceuticals mixed with P-listed or U-listed RCRA pharmaceuticals per the RCRA Land Disposal Restriction requirements
- Hazardous pharmaceuticals after administration and use by a patient are not a listed hazardous waste subject to RCRA, but may be a characteristic hazardous waste and may be included in the Mixed/Medical Dual Guide Sheet as a BMP





Record-Keeping

- Maintain records at least three years
- Waste characterization determination (most likely from facility pharmaceutical formulary analysis) and support records (MSDS)
- Monthly waste inventory
- Land disposal restriction notifications
- Maintain Uniform Hazardous Waste Manifest copies and send copy to the MDEQ by 10th day of month following shipment
- Medical Waste Management Plan
- Accumulation area inspection logs
- Training records

Note: Materials managed as Mixed Medical/Dual Pharm must be included in the monthly hazardous waste generator status determination.